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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,844	07/27/2005	Deepak Murpani	RLL-282US	9372

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,844	MURPANI ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/27/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 9 and 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically claims 9 and 31, recites that the polymer includes a dimethylaminoethyl group, independent claims 1 and 25 already recite that the cationic polymer is synthesized from dimethylaminoethyl methacrylate, thus it is inherent that the polymer already contains a dimethylaminoethyl methacrylate, thus the claims fail to further limit the independent claims.

Claim 16 objected to because of the following informalities: there is a letter "f" in line two, the examiner believed the typo should have read "of" and interpreted the claims as such. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically within claim 6 the recitation that the drug comprises "one or more unpleasant tasting drugs" is considered indefinite to respect to

what drugs are encompassed and what drugs are excluded by the limitation. For instance taste is subjective and is determined by the person consuming the product, for example while some people may like the taste of beets other people would consider them to have an unpleasant taste. Thus since some drugs could be perceived by some to have an unpleasant taste to some and may not offer a noticeably bad taste to others the limitation is indefinite in regards to what drugs would be considered unpleasant tasting.

Claims 11-14,33-34 and 38-39 contains the trademark/trade name Eudragit. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of **35 U.S.C. 112**, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe cationic polymers and, accordingly, the identification/description is indefinite.

Claim 18 recites the limitation "drug solution/dispersion" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13,15-17 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cumming et al. (WO 99/17742, cited by applicants).

Cummings teaches a taste masked micromatrix powder in the form of a sprinkle, suspension, chewable or effervescent tablet, in which the ratio of cationic polymer (including Eudragit E-100) to drug (including several claimed by applicants such as nizatidine, roxadine and loperamide and others) was most preferably 6 to 1; less than applicants claimed upper limit. See abstract, pag 2 lin 26-32, pag 3 lin 26-pag 4 lin 2, pag 5 lin 1-30, examples and claims. Regarding claims 15-17 the examples of Cumming specifically mention the use of cellulose acetate butyrate, ethyl cellulose as retarding polymers and magnesium stearate as an excipient. See examples especially table 2 and pag 10 lin 20-22. Regarding claims 22-24 Cummings specifically mentions the use of a flavoring agent. See examples especially pag 6 lin 14-15.

Claims 1-7,9-13,15-16,18-19,21-25 and 30-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsiao (US 4,708,867, cited by applicants).

Hsiao teaches minipellets comprising prednisone or predisolone coated unto a nonpareil seed and further coated with a layer of dimethylaminoethyl and methyl methacrylate copolymer (including Eudragit E-100). See abstract col 1 lin 9-col 2 lin 34 and claims. Regarding the limitations on the ratio of drug to polymer, Hsiao used 288

grams of E-100 and 80 grams of prednisone, the ratio taught within Hsiao is 1:3.6 lower than applicants claimed upper limit. Regarding claims 15-16 and 23-24 Hsiao specifically recites the use of separation substances such as talc, magnesium stearate and pigments. Regarding claim 21, Hsiao specifically teaches that the mesh size of the nonpareil sugar seeds have a mesh size between 35-40, as evidenced by **www.sigmaldrich.com** a mesh size of 35 to 40 would be a particle size between 420-500 microns, higher than applicants claimed lower limit. Regarding claim 30 Hsiao specifically recites the use of isopropyl alcohol in preparing the coated minipellets.

Claims 1-3,9-13,15-25 and 31-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Dansereau et al. (US 5,049,374).

Dansereau teaches an orally administrable coated bead containing an inert core (can be comprised of mannitol) with a coating that contains sodium iodide I-131a known marker in nuclear magnetic medicine (also a well known antioxidant and antithyroid) and a polymer film that can contain a mixture of hydropropylmethyl cellulose and ethyl cellulose and/or methacrylic acid esters including Eudragit E-100. See col 2 lin 27-col 3 lin 30, examples (especially example 2) and claims. Regarding the limitations on the drug:polymer ratio, from the examples only a trace amount of Iodide was employed thus it is inherent that the drug:polymer ratio of Dansereau would be less than applicants claimed upper limit. Regarding claim 21 Dansereau specifically mentions that the inert substrate beads are most preferably in a range of 400-700 microns higher than applicants claimed lower limit. Regarding claims 23-24 Dansereau specifically mentions the use of fillers, pigments and dyes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cumming et al. (WO 99/17742, cited by applicants).

Cummings is disclosed above, however the reference is silent on the use of the cationic polymer Eudragit EPO as claimed in dependent claim 14. Eudragit E-100 is the preferred type of E polymer however it would have been obvious to one of ordinary skill in the art at the time of applicants claimed invention that other cationic Eudragit type E polymers including Eudragit EPO could be used as the cationic polymer. One of ordinary skill in the art would understand that cationic Eudragit polymers such E100 is interchangeable with Eudragit EPO because they are both related to being cationic dimethylaminoethyl methacrylate copolymers. This is further evidenced by the Eudragit product catalog provided by the examiner, which clearly shows that Eudragit E-100 and EPO are the same type of cationic polymers, useful in the same endeavor. Thus the claimed invention would have been *prima facie* obvious because the substitution of one known element such as Eudragit EPO disclosed within a catalog for another known element such as Eudragit E-100 disclosed within Cumming would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 1-7,9-13,15-16,18-19 and 21-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsiao (US 4,708,867) in view of Patel et al (US 2003/0180352 A1).

Hsiao is disclosed above. Hsiao is silent on the specific methods such as spray coating, granulation and coacervation to coat the inert cores as claimed in dependent claims 26-29.

Patel discloses pharmaceutical compositions active ingredients coated on an inert core. See abstract, [0274], [0288],[0313]. Patel is used primarily for the disclosure

within that processing using the techniques of coacervation, granulation and spray-drying were already well known at the time of applicants claimed invention to be useful techniques when formulating coatings for a pharmaceutical preparation. See [0049],[0235],[0272]. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 1-7,9-13,15-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Dansereau et al. (US 5,049,374) in view of Patel et al (US 2003/0180352 A1) in view of Hsiao (US 4,708,867).

Dansereau is disclosed above. Dansereau is silent on the specific methods such as spray coating, granulation and coacervation to coat the inert cores as claimed in dependent claims 26-29. Dansereau is also silent on the specific solvents used to dissolve the polymer as claimed within dependent claim 30.

Patel is diclsosed above and is used primarily for the disclosure within that processing using the techniques of coacervation, granulation and spray-drying were already well known at the time of applicants claimed invention to be useful techniques when formulating coatings for a pharmaceutical preparation. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would

have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Hsiao is disclosed above and is used primarily for the disclosure within that Eudragit E100 copolymers were well known at the time of applicants claimed invention to be soluble in isopropyl alcohol, the solution being applied as a coat to an inert-core. Thus the claimed invention would have been *prima facie* obvious because the substitution of one known element such as isopropyl alcohol solvent disclosed within Hsiao for another known element such as the solvent (water) disclosed within Dansereau would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618